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Environmental Testing of a Blood Gas/pH and Electrolyte Analyzer for Field Hospital Use

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In 1983 the U.S. Army Academy of Health Sciences developed a Letter Requirement for a Blood Gas/pH Analyzer for use in Echelon 3 and 4 facilities. Field trials of several nondevelopment items and a subsequent market survey did not produce a suitable instrument. Recently, a relatively small, lightweight, and simple device became commercially available, and was tested for field applicability in accordance with MIL-STD-810D. Results indicated that with minor modifications, the instrument would be sufficiently rugged to withstand the severe storage temperature extremes and transit shock and vibration conditions associated with deployment of field medical materiel.

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Introduction

Arterial blood gas analysis is an important tool for making diagnoses and therapeutic decisions regarding trauma patients.[1] The U.S. Army has a requirement for an automated blood gas/pH analyzer in corps-level hospitals, area medical laboratory detachments, and communications zone hospitals, but available models are not sufficiently small, simple to use, durable, and reliable for harsh field conditions. Conventional blood gas analyzers weigh 50 to 100 pounds and have external volumes ranging from 2.3 to 6.4 cubic feet. It is not feasible to package these delicate instruments in standard medical chests such that they can withstand field transit shock and vibration. Also, despite considerable improvements in electrode design and maintenance procedures over the last several years, present analyzers are still considered impractical for combat zone laboratories.[2]

In 1986, a new blood gas/pH and electrolyte analyzer, the GEM-6, that appeared ideally suited for field use because of the design concept utilized was marketed. All wet chemistry components were incorporated into one disposable cartridge,

which eliminated the need for labor-intensive tasks associated with many conventional analyzers (e.g., refurbishing electrode membranes). The design also minimized tubing, valves, and other moving parts, making it inherently more durable and reliable. Although its operational costs (excluding labor) were much higher than for conventional instruments, the GEM-6 was selected for evaluation because it appeared to be the only blood gas analyzer that would come close to meeting the Essential Characteristics (ECs) for size, maintainability, and durability. An additional point to consider was that it also measured electrolytes, potentially eliminating the need for other instruments.

Research to assess the clinical efficacy of the instrument had already been conducted,[3] with favorable results. A later study further verified the device's accuracy over the clinically important range, although accuracy was reduced for extremely high values of arterial oxygen tension.[4] No durability data was available, however, so environmental testing was conducted to determine whether the instrument would be sufficiently durable for fielding by the U.S. Army.

Materials and Methods

The instrument studied (Fig. 1) was the GEM-6 Portable Blood Gas Analyzer (Mallinckrodt Sensor Systems, Ann Arbor, Michigan). The unit weights 28 pounds and has external dimensions of 9 by 17¾ by 8⅜ inches, for a volume of 0.77 cubic feet. It measures pH, partial pressures of oxygen, and carbon dioxide (Po_2, Pco_2), concentrations of ionized potassium (K^+) and calcium (Ca^{2+}), hematocrit and temperature (A newer

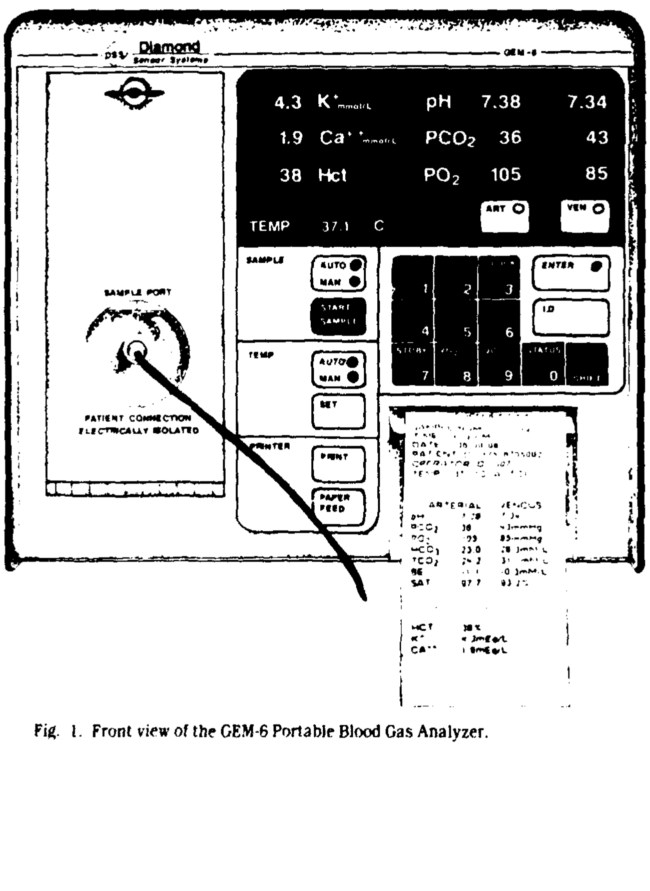

Fig. 1. Front view of the GEM-6 Portable Blood Gas Analyzer.

model (GEM-STAT) also measures ionized sodium). It derives base excess, bicarbonate, total carbon dioxide, and oxygen saturation of hemoglobin. Features include numeric displays for each measured parameter; an alphanumeric display for providing instrument status information, keyboard prompts, and other information; a membrane switch panel for command and data entry; automatic hard copy printout; and patient temperature correction capability. Auxiliary battery backup is also provided to maintain a memory of programmed instructions and data generated for up to 30 minutes.

The degree of automation of the GEM-6 makes it extremely simple to operate. A 45-minute warm-up period begins automatically upon insertion of a disposable GEM-PAK sensor/reagent cartridge (2 by 5 by 7.8 inches). The cartridge contains electrochemical sensors, calibrating and flush solutions, and a waste container. No compressed gases are required, as they are with conventional blood gas analyzers. Upon operator command, a fixed volume of sample is aspirated, equilibrated to 37°C, and analyzed for all measured/derived parameters within 130 seconds. Each cartridge contains sufficient calibration and flush solutions to process up to 50 samples, at a maximum throughput of 11 samples per hour, or 50 in 4½ hours. The samples can be distributed as needed over the cartridge's "active" life of 8 hours, or if lengthy periods of inactivity are anticipated, the "standby" mode can be invoked to extend the cartridge life to as much as 36 hours (For the GEM-STAT, the cartridge life is extended to 48 hours). Two-point calibrations are performed automatically 20 minutes after completion of the warm-up period and at 1 hour intervals throughout the remainder of the cartridge active life. A one-point calibration and rinse cycle is performed automatically after each sample analysis.

GEM-CHECK quality control solutions are available for operational verification of analyzer and cartridge function. They are provided in three levels representing different patient conditions: acidosis (low level), normal values (normal level), and alkalosis (high level). Thirty ampules (10 per level) are supplied per box of quality controls.

Environmental testing of the blood gas analyzer and associated supplies included subjecting the packaged items to field-simulated high and low storage temperatures, vibration, and shock, in accordance with MIL-STD-810D, *Environmental Test Methods and Engineering Guidelines*,[5] Methods 501.2 (I), 502.2 (I), 514.3 (I), and 516.3 (IV). During the environmental tests, the blood gas analyzer was packaged in 2.0 pound/ft^3 polyurethane foam (Roger's Foam Corporation, Sharon Hill, PA) inside a Chest, Field, Aluminum, Size 6 (NSN 6545-00-914-3510). A size 6 container has interior dimensions of 30¼ by 18¼ by 20¼ inches and is the maximum size protective container acceptable under the ECs. Cushion design was based on a typical fragility for medical electronic equipment of 40 g peak acceleration.[6] Bearing areas and thicknesses were designed to satisfy shock mitigation requirements for a 30-inch drop, using applicable cushioning curve data[7] and accounting for creep. Because the ECs do not include specifications on packaging constraints for consumable supplies, the supplies were packaged separately for testing convenience.

For the temperature testing, the items were placed in an environmental test chamber (Bemco, Inc., Pacoima, California) and exposed for 24 hours to temperature extremes of 70°C or

−54°C for the hot and cold climatic design-type conditions.[5] Vibration testing was conducted by placing the items on a Model 826 High Frequency Vibration Machine (Ling, Inc., Yalesville, Connecticut), and subjecting them to the vibration spectrum for an M548 Tracked Vehicle. Shock testing consisted of dropping the items once on each face from a height of 30 inches onto a wood platform using a Gaynes Drop Tester (Gaynes Engineering Co., Franklin Park, Illinois).

The items' susceptibility to each of the environmental test conditions were evaluated individually to isolate potential causes of failure. Therefore, when the analyzer was subjected to a test condition, untreated supplies were used to evaluate its subsequent performance. Similarly, when cartridges were subjected to test conditions, untreated quality controls were used, and vice versa. Because of the potential chemical effects of temperature testing, untreated quality controls were studied concurrently with the temperature-exposed controls to verify proper cartridge and analyzer operation during those tests.

Nine GEM-PAK cartridges were tested, using all three levels of GEM-CHECK quality control solutions as samples. Expected results for the controls studied are shown in Tables I and II. All controls were of the same lot number except the box used on the cartridge exposed to high storage temperature conditions. All parameters measured by the GEM-6 were studied except hematocrit, for which the measurement principle (conductivity) is not reliable.[2] (Future versions of this technology that correct for sodium concentration may produce more reliable readings,[4] but for the present, use of the hematocrit electrode over spun hematocrit is discouraged.)

When possible, samples were processed throughout the entire 36-hour cartridge life to enable a comparison of performance following warm-up to performance following a long period in standby. An initial functional evaluation of the instrument was conducted using the first (control) cartridge, to verify cartridge life, samples per cartridge, throughput, and performance following a 30-minute power loss. Subsequent cartridges involved some aspect of environmental testing related to storage or transit conditions.

TABLE I

EXPECTED MEANS FOR GEM-CHECK QUALITY CONTROL SOLUTIONS USED FOR ALL ENVIRONMENTAL TEST CONDITIONS (EXCEPT HOT CARTRIDGE TEST) ON A GEM-6 PORTABLE BLOOD GAS/ELECTROLYTE ANALYZER

	Expected Mean				
Level	pH	P_{CO_2} (mm Hg)	P_{O_2} (mm Hg)	K^+ (mmol/L)	Ca^{2+} (mmol/L)
Low	7.05	77	62	2.5	0.9
Normal	7.35	47	113	3.9	1.2
High	7.57	22	160	6.3	1.6

TABLE II

EXPECTED MEANS FOR GEM-CHECK QUALITY CONTROL SOLUTIONS USED FOR HOT CARTRIDGE ENVIRONMENTAL TEST ON A GEM-6 PORTABLE BLOOD GAS/ELECTROLYTE ANALYZER

	Expected Mean				
Level	pH	P_{CO_2} (mm Hg)	P_{O_2} (mm Hg)	K^+ (mmol/L)	Ca^{2+} (mmol/L)
Low	7.04	77	63	2.5	0.9
Normal	7.35	47	115	3.9	1.2
High	7.56	22	162	6.4	1.6

Results

Overall, the test items performed well, although several minor problems were identified. All results (Tables III through V) were within the tolerance ranges specified by the manufacturer except for those indicated in Table VI.

Data from the control cartridge indicated that the blood gas analyzer was functioning within the manufacturer's guidelines prior to exposure to environmental test conditions. No problems with electrode drift following long periods in standby mode were observed, and the device functioned correctly following a 30-minute power loss.

High temperature storage testing of the analyzer resulted in failure of a component associated with the analyzer's heater block, which maintains the sensor array at 37°C. Since measurements are incorrect when the analysis is not performed at

TABLE III

RESULTS ON ENVIRONMENTAL TESTING OF GEM-6 PORTABLE BLOOD GAS/PH AND ELECTROLYTE ANALYZER LOW LEVEL QUALITY CONTROLS: ACIDOSIS (I)

Treatment	pH	P_{CO_2} (mm Hg)	P_{O_2} (mm Hg)	K^+ (mmol/L)	Ca^{2+} (mmol/L)
Controls	7.06 ± 0.0005[a]	74.6 ± 0.17	65.9 ± 0.44	2.58 ± 0.003	0.91 ± 0.001
Hot cartridge	7.06 ± 0.0029	79.2 ± 0.83	66.2 ± 0.40	2.61 ± 0.010	0.87 ± 0.005
Cold cartridge	7.09 ± 0.0006	76.7 ± 0.26	66.4 ± 0.67	2.55 ± 0.005	4.40 ± 0.028
Controls/temperature quality controls[b]	7.06 ± 0.0017	76.8 ± 0.52	67.2 ± 0.30	2.58 ± 0.009	0.84 ± 0.011
Hot quality controls	7.05 ± 0.0011	80.8 ± 0.36	63.8 ± 0.59	2.56 ± 0.023	0.84 ± 0.011
Cold quality controls	7.04 ± 0.0000	81.4 ± 0.30	62.6 ± 0.59	2.58 ± 0.009	0.66 ± 0.011
Vibration analyzer	7.07 ± 0.0017	73.8 ± 0.36	64.8 ± 0.99	2.56 ± 0.011	0.92 ± 0.009
Vibration quality controls	7.05 ± 0.0005	78.8 ± 0.15	62.9 ± 0.43	2.58 ± 0.004	0.89 ± 0.003
Shock analyzer	7.05 ± 0.0013	79.3 ± 0.63	64.3 ± 1.78	2.58 ± 0.013	0.85 ± 0.014
Shock quality controls	7.06 ± 0.0010	80.6 ± 0.49	61.3 ± 1.13	2.59 ± 0.008	0.85 ± 0.007

[a] Values are means ± standard errors.

[b] Untreated quality controls used to verify analyzer/cartridge performance when studying hot/cold quality control tests.

TABLE IV

RESULTS ON ENVIRONMENTAL TESTING OF GEM-6 PORTABLE BLOOD GAS/PH AND ELECTROLYTE ANALYZER NORMAL LEVEL QUALITY CONTROLS: NORMAL (II)

Treatment	pH	Pco_2 (mm Hg)	Po_2 (mm Hg)	K^+ (mmol/L)	Ca^{2+} (mmol/L)
Controls	7.37 ± 0.0003[a]	47.1 ± 0.06	113.3 ± 0.31	3.91 ± 0.002	1.24 ± 0.003
Hot cartridge	7.33 ± 0.0027	48.5 ± 0.27	117.6 ± 0.34	3.94 ± 0.009	1.14 ± 0.006
Cold cartridge	7.41 ± 0.0005	47.4 ± 0.10	111.8 ± 0.28	3.87 ± 0.004	7.88 ± 0.057
Controls/temperature quality controls[b]	7.34 ± 0.0000	47.6 ± 0.18	113.4 ± 0.66	3.88 ± 0.009	1.10 ± 0.000
Hot quality controls	7.34 ± 0.0000	48.0 ± 0.14	112.6 ± 0.23	3.92 ± 0.022	1.12 ± 0.009
Cold quality controls	7.32 ± 0.0000	48.6 ± 0.18	113.4 ± 0.73	3.90 ± 0.000	0.48 ± 0.017
Vibration analyzer	7.34 ± 0.0011	47.2 ± 0.09	113.0 ± 0.55	3.90 ± 0.000	1.22 ± 0.009
Vibration quality controls	7.34 ± 0.0005	47.4 ± 0.05	113.2 ± 0.35	3.88 ± 0.006	1.20 ± 0.000
Shock analyzer	7.34 ± 0.0013	47.5 ± 0.14	111.3 ± 1.14	3.90 ± 0.000	1.13 ± 0.024
Shock quality controls	7.34 ± 0.0007	47.8 ± 0.20	112.9 ± 0.73	3.93 ± 0.006	1.13 ± 0.011

[a] Values are means ± standard errors.

[b] Untreated quality controls used to verify analyzer/cartridge performance when studying hot/cold quality control tests.

TABLE V

RESULTS ON ENVIRONMENTAL TESTING OF GEM-6 PORTABLE BLOOD GAS/PH AND ELECTROLYTE ANALYZER HIGH LEVEL QUALITY CONTROLS: ALKALOSIS (III)

Treatment	pH	Pco_2 (mm Hg)	Po_2 (mm Hg)	K^+ (mmol/L)	Ca^{2+} (mmol/L)
Controls	7.59 ± 0.0003[a]	20.8 ± 0.04	157.9 ± 0.43	6.20 ± 0.006	1.72 ± 0.004
Hot cartridge	7.53 ± 0.0006	21.0 ± 0.18	168.9 ± 0.28	6.14 ± 0.005	1.51 ± 0.003
Cold cartridge	7.64 ± 0.0004	20.6 ± 0.06	161.5 ± 0.20	6.05 ± 0.007	14.51 ± 0.083
Controls/temperature quality controls[b]	7.55 ± 0.0009	20.0 ± 0.00	159.2 ± 0.55	6.08 ± 0.009	1.54 ± 0.011
Hot quality controls	7.55 ± 0.0009	20.0 ± 0.00	160.6 ± 0.59	6.12 ± 0.009	1.52 ± 0.009
Cold quality controls	7.51 ± 0.0000	20.6 ± 0.11	157.6 ± 0.30	6.14 ± 0.011	0.44 ± 0.011
Vibration analyzer	7.55 ± 0.0014	21.2 ± 0.09	160.6 ± 0.41	6.12 ± 0.009	1.68 ± 0.009
Vibration quality controls	7.55 ± 0.0004	20.4 ± 0.05	161.5 ± 0.16	6.10 ± 0.007	1.65 ± 0.005
Shock analyzer	7.55 ± 0.0021	19.8 ± 0.13	174.8 ± 9.04	6.25 ± 0.025	1.55 ± 0.014
Shock quality controls	7.55 ± 0.0007	19.9 ± 0.04	161.0 ± 0.52	6.19 ± 0.004	1.54 ± 0.009

[a] Values are means ± standard errors.

[b] Untreated quality controls used to verify analyzer/cartridge performance when studying hot/cold quality control tests.

TABLE VI

OCCURRENCE OF OUTLIERS IN ENVIRONMENTAL TESTING OF GEM-6 PORTABLE BLOOD GAS/ELECTROLYTE ANALYZER

		Number of outliers			
Treatment	N[a]	pH	Pco_2	Po_2	Ca^{2+}
Controls	50	—	—	4[b]	—
Hot cartridge	28	2	2	1	—
Cold cartridge	33	22	—	1	33
Cold quality controls	15	5	—	—	10
Shock analyzer	12	—	—	2	—
Shock quality controls	24	—	—	2	—

[a] Number of samples.

[b] Three of these four outliers occurred on samples that were not at room temperature.

the required temperature, testing was terminated after two samples, and these results are not presented.

While the manufacturer investigated the heater block failure, a loaner device was used to test the supplies exposed to storage temperature extremes. A high storage temperature did not appear to affect the means for the cartridge or quality controls, although there did appear to be greater variation in pH and Pco_2. Low storage temperature significantly affected the Ca^{2+} and pH values. For the cartridge that had been frozen, the values of Ca^{2+} and pH were high, and for the quality controls that had been frozen, these values were low. Results showed that measurements of the other three parameters (Pco_2, Po_2, and K^+) were unaffected by freezing.

Vibration and shock testing did not damage the quality control ampules, but did cause leakage of the cartridges at the calibration solution bag-fluid dispersion valve interface (Fig. 2). No samples were run on these damaged cartridges.

The original GEM-6 instrument was returned for shock and vibration testing, and survived both test regimens with no significant damage other than the following minor problem after the shock tests. After approximately 26 hours of cartridge operation (and 36 sample analyses), the message "insert cartridge" erroneously appeared on the alphanumeric display. This message is supposed to appear after the power is turned on and the instrument completes its self-diagnostics, or following removal of a cartridge. To return the instrument to its operating mode and determine whether the problem was tran-

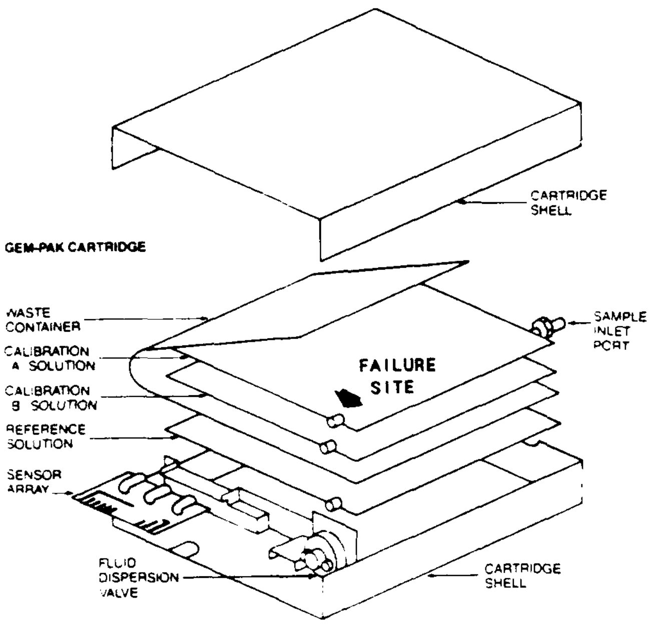

Fig. 2. Site of failure on the GEM-PAK cartridges subjected to shock and vibration.

sient, the door to the cartridge chamber was opened and closed, initiating a new warm-up period. The remaining samples were later analyzed, verifying that the mechanical problem was corrected. Results for those samples are not presented. Another problem encountered with this (untreated) cartridge was considerable variability in the high-level Po_2 values, evident from the value of standard error shown in Table V.

Discussion

The problems incurred during environmental testing are resolvable, such that the GEM-6 (or GEM-STAT) and associated supplies could be fielded with minimal changes and restrictions. Overall, temperature will pose more of a problem than transit shock and vibration.

Failure of the heater block following the high temperature test condition was caused by a tripped circuit breaker, which prevented the heater block from receiving power. The manufacturer suggested resolving this problem by replacing the circuit breaker with a standard fuse.

Cold temperature exposure of the cartridge and quality control solutions caused calcium carbonate to precipitate, which invalidated the results for calcium and also shifted the pH, particularly in the solutions containing the most calcium. Although no physical damage was discovered as a result of freezing, it is possible that expansion of the cartridge calibration solutions could fracture the valve assembly, thereby causing leakage of the calibration solutions. In view of these chemical and mechanical considerations, protection of the blood gas analyzer cartridges and quality controls from freezing is implicated. Protection from extremely high temperatures is advisable as well, because of the potential reduction in shelf life, as occurs with many other reagents when exposed to high temperatures.

The problem encountered with the "insert cartridge" message following shock testing is believed to be a hardware problem with one of the switches that senses the presence of a cartridge (one in the sensor array, and one in the cartridge chamber door). Since this condition was easily remedied by the operator, it should not prevent fielding of the device. The problem with Po_2 measurements on that same cartridge was attributed to a bad Po_2 electrode, because that cartridge was untreated.

Leakage problems with the cartridges due to transit conditions are a major concern. The manufacturer has since redesigned the bag-valve interface to eliminate the stress concentration, which should eliminate future problems with cartridge durability. These new cartridges should be tested if the GEM-6 (or GEM-STAT) is to be fielded.

The short shelf life of the cartridges (6 months) is a further concern; however, the manufacturer has an ongoing program to increase the shelf life to a year or more, so this problem may eventually be alleviated. For now, refrigeration can be used to extend the shelf life, if necessary.

Although clinical studies on the analyzer were not a part of this study, the device has undergone evaluation at Brooke Army Medical Center (San Antonio, TX) by a group of anesthesiologists. The users found that the results from the GEM-6 correlate closely with their standard blood gas analyzer from Instrumentation Laboratories. No mechanical problems were experienced over 6 weeks and the device was found to be very easy to use.

Conclusions

The GEM-6 blood gas analyzer performed reasonably well following exposure to field-relevant environmental test conditions. Either it or the GEM-STAT would be sufficiently durable for use by the U.S. Army, provided that several modifications are implemented and constraints imposed. Modifications include replacement of the circuit breaker for the heater block board with a standard fuse, and redesign of the calibration bag-fluid dispersion valve interface in the cartridges (which the company has since done). If the constraint of protecting consumable supplies from temperature extremes is possible, the analyzer would then be deployable and a valuable asset to field medicine.

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